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Exhibit 169A

Public Law 110–85
110th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

Sept. 27, 2007
[H.R. 3580]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

Food and Drug Administration Amendments Act of 2007.
21 USC 301 note.

This Act may be cited as the "Food and Drug Administration Amendments Act of 2007".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

Prescription Drug User Fee Amendments of 2007.

SEC. 101. SHORT TITLE; REFERENCES IN TITLE; FINDING.

21 USC 301 note.

(a) SHORT TITLE.—This title may be cited as the "Prescription Drug User Fee Amendments of 2007".

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

21 USC 379g note.

(c) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the matter before paragraph (1), by striking "For purposes of this subchapter" and inserting "For purposes of this part";

(2) in paragraph (1)—

(A) in subparagraph (A), by striking "505(b)(1)," and inserting "505(b), or";

(B) by striking subparagraph (B);

(C) by redesignating subparagraph (C) as subparagraph (B); and

(D) in the matter following subparagraph (B), as so redesignated, by striking "subparagraph (C)" and inserting "subparagraph (B)";

(3) in paragraph (3)(C)—

(A) by striking "505(j)(7)(A)" and inserting "505(j)(7)(A) (not including the discontinued section of such list)"; and

(B) by inserting before the period "(not including the discontinued section of such list)";

(4) in paragraph (4), by inserting before the period at the end the following: "(such as capsules, tablets, or lyophilized products before reconstitution)";

(5) by amending paragraph (6)(F) to read as follows:

"(F) Postmarket safety activities with respect to drugs approved under human drug applications or supplements, including the following activities:

"(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

"(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

"(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

"(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

"(v) Carrying out section 505(k)(5) (relating to adverse event reports and postmarket safety activities).";

(6) in paragraph (8)—

(A) by striking "April of the preceding fiscal year" and inserting "October of the preceding fiscal year"; and

(B) by striking "April 1997" and inserting "October 1996";

(7) by redesignating paragraph (9) as paragraph (11); and

(8) by inserting after paragraph (8) the following paragraphs:

"(9) The term 'person' includes an affiliate thereof.

"(10) The term 'active', with respect to a commercial investigational new drug application, means such an application to which information was submitted during the relevant period.".

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking "2003" and inserting "2008";

(2) in paragraph (1)—

(A) in subparagraph (D)—

(i) in the heading, by inserting "OR WITHDRAWN BEFORE FILING" after "REFUSED FOR FILING"; and

(ii) by inserting before the period at the end the following: "or withdrawn without a waiver before filing";

(B) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(C) by inserting after subparagraph (D) the following:

"(E) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A human drug application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).."; and

(3) in paragraph (2)—

(A) in subparagraph (A), by striking "subparagraph (B)" and inserting "subparagraphs (B) and (C)"; and

(B) by adding at the end the following:

"(C) SPECIAL RULES FOR POSITRON EMISSION TOMOGRAPHY DRUGS.—

"(i) IN GENERAL.—Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a positron emission tomography drug shall be subject under subparagraph (A) to one-sixth of an annual establishment fee with respect to each such establishment identified in the application as producing positron emission tomography drugs under the approved application.

"(ii) EXCEPTION FROM ANNUAL ESTABLISHMENT FEE.—Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

"(I) the person is a not-for-profit medical center that has only 1 establishment for the production of positron emission tomography drugs; and

"(II) at least 95 percent of the total number of doses of each positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.

"(iii) DEFINITION.—For purposes of this subparagraph, the term 'positron emission tomography drug' has the meaning given to the term 'compounded positron emission tomography drug' in section 201(ii), except that paragraph (1)(B) of such section shall not apply.".

(b) FEE REVENUE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE REVENUE AMOUNTS.—

"(1) IN GENERAL.—For each of the fiscal years 2008 through 2012, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

"(A) $392,783,000; and

"(B) an amount equal to the modified workload adjustment factor for fiscal year 2007 (as determined under paragraph (3)).

"(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

"(A) one-third shall be derived from fees under subsection (a)(1) (relating to human drug applications and supplements);

"(B) one-third shall be derived from fees under subsection (a)(2) (relating to prescription drug establishments); and

"(C) one-third shall be derived from fees under subsection (a)(3) (relating to prescription drug products).

"(3) MODIFIED WORKLOAD ADJUSTMENT FACTOR FOR FISCAL YEAR 2007.—For purposes of paragraph (1)(B), the Secretary shall determine the modified workload adjustment factor by determining the dollar amount that results from applying the methodology that was in effect under subsection (c)(2) for fiscal year 2007 to the amount $354,893,000, except that, with respect to the portion of such determination that is based on the change in the total number of commercial investigational new drug applications, the Secretary shall count the number of such applications that were active during the most recent 12-month period for which data on such submissions is available.

Applicability.

"(4) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—

"(A) IN GENERAL.—For each of the fiscal years 2008 through 2012, paragraph (1)(A) shall be applied by substituting the amount determined under subparagraph (B) for '$392,783,000'.

"(B) AMOUNT DETERMINED.—For each of the fiscal years 2008 through 2012, the amount determined under this subparagraph is the sum of—

"(i) $392,783,000; plus

"(ii)(I) for fiscal year 2008, $25,000,000;

"(II) for fiscal year 2009, $35,000,000;

"(III) for fiscal year 2010, $45,000,000;

"(IV) for fiscal year 2011, $55,000,000; and

"(V) for fiscal year 2012, $65,000,000.".

(c) ADJUSTMENTS TO FEES.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

(A) in the matter preceding subparagraph (A), by striking "The revenues established in subsection (b)" and inserting "For fiscal year 2009 and subsequent fiscal years, the revenues established in subsection (b)";

(B) in subparagraph (A), by striking "or" at the end;

(C) in subparagraph (B), by striking the period at the end and inserting ", or";

(D) by inserting after subparagraph (B) the following:

"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years."; and

(E) in the matter following subparagraph (C) (as added by subparagraph (D)), by striking "fiscal year 2003" and inserting "fiscal year 2008".

(2) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

(A) in the matter preceding subparagraph (A), by striking "Beginning with fiscal year 2004," and inserting "For fiscal year 2009 and subsequent fiscal years,";

(B) in subparagraph (A), in the first sentence—

(i) by striking "human drug applications," and inserting "human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph),";

(ii) by striking "commercial investigational new drug applications,"; and

(iii) by inserting before the period the following: ", and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available";

(C) in subparagraph (B), by adding at the end the following: "Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activities."; and

(D) by adding at the end the following:

"(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in review activities applied in setting fees and revenue amounts for fiscal year 2009 and to make recommendations, if warranted, for future changes in the methodology for calculating the adjustment. After review of the recommendations, the Secretary shall, if warranted, make appropriate changes to the methodology, and the changes shall be effective for each of the fiscal years 2010 through 2012. The Secretary shall not make any adjustment for changes in review activities for any fiscal year after 2009 unless such study has been completed.". Contracts. Study. Effective date.

(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and

(B) by inserting after paragraph (2) the following:

"(3) RENT AND RENT-RELATED COST ADJUSTMENT.—For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, before making adjustments under paragraphs (1) and (2), decrease the fee revenue amount established in subsection (b) if actual costs paid for rent and rent-related expenses for the preceding fiscal year are less than estimates made for such year in fiscal year 2006. Any reduction made under this paragraph shall not exceed the amount by which such costs fall below the estimates made in fiscal year 2006 for such fiscal year, and shall not exceed $11,721,000 for any fiscal year.".

(4) FINAL YEAR ADJUSTMENT.—Paragraph (4) of section 736(c) (21 U.S.C. 379h(c)), as redesignated by paragraph (3)(A), is amended to read as follows:

"(4) FINAL YEAR ADJUSTMENT.—

"(A) INCREASE IN FEES.—For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2013. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2012. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

"(B) DECREASE IN FEES.—

"(i) IN GENERAL.—For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), decrease the fee revenues and fees established in subsection (b) by the amount determined in clause (ii), if, for fiscal year 2009 or 2010—

"(I) the amount of the total appropriations for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriations for the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1); and

"(II) the amount of the total appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1).

"(ii) AMOUNT OF DECREASE.—The amount determined in this clause is the lesser of—

"(I) the amount equal to the sum of the amounts that, for each of fiscal years 2009 and 2010, is the lesser of—

"(aa) the excess amount described in clause (i)(II) for such fiscal year; or

"(bb) the amount specified in subsection (b)(4)(B)(ii) for such fiscal year; or

"(II) $65,000,000.

"(iii) LIMITATIONS.—

"(I) FISCAL YEAR CONDITION.—In making the determination under clause (ii), an amount described in subclause (I) of such clause for fiscal year 2009 or 2010 shall be taken into account

only if subclauses (I) and (II) of clause (i) apply to such fiscal year.

"(II) RELATION TO SUBPARAGRAPH (A).—The Secretary shall limit any decrease under this paragraph if such a limitation is necessary to provide for the 3 months of operating reserves described in subparagraph (A).".

(5) LIMIT.—Paragraph (5) of section 736(c) (21 U.S.C. 379h(c)), as redesignated by paragraph (3)(A), is amended by striking "2002" and inserting "2007".

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A)—

(A) by inserting after "The Secretary shall grant" the following: "to a person who is named as the applicant in a human drug application"; and

(B) by inserting "to that person" after "one or more fees assessed";

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(3) by inserting after paragraph (1) the following:

"(2) CONSIDERATIONS.—In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant."; and

(4) in paragraph (4) (as redesignated by paragraph (2)), in subparagraph (A), by inserting before the period the following: ", and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce".

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4) of this subsection.".

(2) OFFSET.—Section 736(g)(4) (21 U.S.C. 379h(g)(4)) is amended to read as follows:

"(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2008 through 2010 and the amount of fees estimated to be collected under this section for fiscal year 2011 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2008 through 2011, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.".

(f) EXEMPTION FOR ORPHAN DRUGS.—Section 736 (21 U.S.C. 379h) is further amended by adding at the end the following:

"(k) ORPHAN DRUGS.—

"(1) EXEMPTION.—A drug designated under section 526 for a rare disease or condition and approved under section 505 or under section 351 of the Public Health Service Act shall be exempt from product and establishment fees under this section, if the drug meets all of the following conditions:

"(A) The drug meets the public health requirements contained in this Act as such requirements are applied to requests for waivers for product and establishment fees.

"(B) The drug is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue during the previous year.

"(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed $50,000,000 for the preceding 12 months before the exemption was requested.".

(g) CONFORMING AMENDMENT.—Section 736(a) (21 U.S.C. 379h(a)) is amended in paragraphs (1)(A)(i), (1)(A)(ii), (2)(A), and (3)(A) by striking "(c)(4)" each place such term appears and inserting "(c)(5)".

(h) TECHNICAL AMENDMENT.—

(1) AMENDMENT.—Section 736(g)(1) (21 U.S.C. 379h(g)(1)) is amended by striking the first sentence and inserting the following: "Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.".

21 USC 379h note.

(2) EFFECTIVE DATE.—Paragraph (1) shall take effect as if included in section 504 of the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188; 116 Stat. 687).

SEC. 104. FEES RELATING TO ADVISORY REVIEW OF PRESCRIPTION-DRUG TELEVISION ADVERTISING.

Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.) is amended by adding after section 736 the following:

21 USC 379h–1.

"SEC. 736A. FEES RELATING TO ADVISORY REVIEW OF PRESCRIPTION-DRUG TELEVISION ADVERTISING.

"(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION ADVERTISEMENT REVIEW FEES.—Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

Effective date.

"(1) ADVISORY REVIEW FEE.—

"(A) IN GENERAL.—With respect to a proposed direct-to-consumer television advertisement (referred to in this section as a 'DTC advertisement'), each person that on or after October 1, 2007, submits such an advertisement for advisory review by the Secretary prior to its initial public dissemination shall, except as provided in subparagraph (B), be subject to a fee established under subsection (c)(3).

"(B) EXCEPTION FOR REQUIRED SUBMISSIONS.—A DTC advertisement that is required to be submitted to the Secretary prior to initial public dissemination is not subject to a fee under subparagraph (A) unless the sponsor designates the submission as a submission for advisory review.

"(C) NOTICE TO SECRETARY OF NUMBER OF ADVERTISEMENTS.—Not later than June 1 of each fiscal

Deadlines. Federal Register, publication.

year, the Secretary shall publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of DTC advertisements the person intends to submit for advisory review in the next fiscal year. Notwithstanding the preceding sentence, for fiscal year 2008, the Secretary shall publish such a notice in the Federal Register not later than 30 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007.

"(D) PAYMENT.— Deadlines.

"(i) IN GENERAL.—The fee required by subparagraph (A) (referred to in this section as 'an advisory review fee') shall be due not later than October 1 of the fiscal year in which the DTC advertisement involved is intended to be submitted for advisory review, subject to subparagraph (F)(i). Notwithstanding the preceding sentence, the advisory review fee for any DTC advertisement that is intended to be submitted for advisory review during fiscal year 2008 shall be due not later than 120 days after the date of the enactment of the Food and Drug Administration Amendments of 2007 or an earlier date as specified by the Secretary.

"(ii) EFFECT OF SUBMISSION.—Notification of the Secretary under subparagraph (C) of the number of DTC advertisements a person intends to submit for advisory review is a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. Notwithstanding the preceding sentence, the commitment shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions for fiscal year 2008 by the date specified in clause (i).

"(iii) NOTICE REGARDING CARRYOVER SUBMISSIONS.—In making a notification under subparagraph (C), the person involved shall in addition notify the Secretary if under subparagraph (F)(i) the person intends to submit a DTC advertisement for which the advisory review fee has already been paid. If the person does not so notify the Secretary, each DTC advertisement submitted by the person for advisory review in the fiscal year involved shall be subject to the advisory review fee.

"(E) MODIFICATION OF ADVISORY REVIEW FEE.—

"(i) LATE PAYMENT.—If a person has submitted a notification under subparagraph (C) with respect to a fiscal year and has not paid all advisory review fees due under subparagraph (D) not later than November 1 of such fiscal year (or, in the case of such a notification submitted with respect to fiscal year 2008, not later than 150 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary), the fees shall be regarded as late Applicability.

and an increase in the amount of fees applies in accordance with this clause, notwithstanding any other provision of this section. For such person, all advisory review fees for such fiscal year shall be due and payable 20 days before any direct-to-consumer advertisement is submitted to the Secretary for advisory review, and each such fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

Deadline.

"(ii) EXCEEDING IDENTIFIED NUMBER OF SUBMISSIONS.—If a person submits a number of DTC advertisements for advisory review in a fiscal year that exceeds the number identified by the person under subparagraph (C), an increase in the amount of fees applies under this clause for each submission in excess of such number, notwithstanding any other provision of this section. For each such DTC advertisement, the advisory review fee shall be due and payable 20 days before the advertisement is submitted to the Secretary, and the fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

Deadline.

"(F) LIMITS.—

"(i) SUBMISSIONS.—For each advisory review fee paid by a person for a fiscal year, the person is entitled to acceptance for advisory review by the Secretary of one DTC advertisement and acceptance of one resubmission for advisory review of the same advertisement. The advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over not more than one paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

"(ii) NO REFUNDS.—Except as provided by subsections (d)(4) and (f), fees paid under this section shall not be refunded.

"(iii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

"(iv) RIGHT TO ADVISORY REVIEW NOT TRANSFERABLE.—The right to an advisory review under this paragraph is not transferable, except to a successor in interest.

"(2) OPERATING RESERVE FEE.—

"(A) IN GENERAL.—Each person that on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to fee established under subsection (d)(2) (referred to in this section as an 'operating reserve fee') for the first fiscal year in which an advisory review fee is assessed to such person. The person is not subject to an operating reserve fee for any other fiscal year.

Deadlines.

"(B) PAYMENT.—Except as provided in subparagraph (C), the operating reserve fee shall be due no later than—

"(i) October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1); or

"(ii) for fiscal year 2008, 120 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary.

"(C) LATE NOTICE OF SUBMISSION.—If, in the first fiscal year of a person's participation in the program under this section, that person submits any DTC advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (a)(1)(C), that person shall pay an operating reserve fee for each of those advisory reviews equal to the advisory review fee for each submission established under paragraph (1)(E)(ii). Fees required by this subparagraph shall be in addition to any fees required by subparagraph (A). Fees under this subparagraph shall be due 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review. Deadline.

"(D) LATE PAYMENT.— Deadlines.

"(i) IN GENERAL.—Notwithstanding subparagraph (B), and subject to clause (ii), an operating reserve fee shall be regarded as late if the person required to pay the fee has not paid the complete operating reserve fee by—

"(I) for fiscal year 2008, 150 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary; or

"(II) in any subsequent year, November 1.

"(ii) COMPLETE PAYMENT.—The complete operating reserve fee shall be due and payable 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review.

"(iii) AMOUNT.—Notwithstanding any other provision of this section, an operating reserve fee that is regarded as late under this subparagraph shall be equal to 150 percent of the operating reserve fee that otherwise would have applied pursuant to subsection (d).

"(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—Fees under subsection (a)(1) shall be established to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsections (c) and (g)(4).

"(c) ADJUSTMENTS.—

"(1) INFLATION ADJUSTMENT.—Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of— Effective date. Notice. Federal Register, publication.

"(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

"(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance

with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 fiscal years of the previous 6 fiscal years.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

Effective date.

"(2) WORKLOAD ADJUSTMENT.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of DTC advertisements for advisory review prior to initial dissemination. With respect to such adjustment:

"(A) The adjustment shall be determined by the Secretary based upon the number of DTC advertisements identified pursuant to subsection (a)(1)(C) for the upcoming fiscal year, excluding allowable previously paid carry over submissions. The adjustment shall be determined by multiplying the number of such advertisements projected for that fiscal year that exceeds 150 by $27,600 (adjusted each year beginning with fiscal year 2009 for inflation in accordance with paragraph (1)). The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

Federal Register, publication.

"(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

"(3) ANNUAL FEE SETTING FOR ADVISORY REVIEW.—

Deadlines.

"(A) IN GENERAL.—Not later than August 1 of each fiscal year (or, with respect to fiscal year 2008, not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007), the Secretary shall establish for the next fiscal year the DTC advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under paragraphs (1) and (2), and the number of DTC advertisements identified pursuant to subsection (a)(1)(C), excluding allowable previously-paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue for a fiscal year (as adjusted pursuant to this subsection) by the number of DTC advertisements so identified, excluding allowable previously-paid carry over submissions under subsection (a)(1)(F)(i).

"(B) FISCAL YEAR 2008 FEE LIMIT.—Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for

fiscal year 2008 may not be more than $83,000 per submission for advisory review.

"(C) ANNUAL FEE LIMIT.—Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for a fiscal year after fiscal year 2008 may not be more than 50 percent more than the fee established for the prior fiscal year.

"(D) LIMIT.—The total amount of fees obligated for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the advisory review of prescription drug advertising.

"(d) OPERATING RESERVES.—

"(1) IN GENERAL.—The Secretary shall establish in the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation a Direct-to-Consumer Advisory Review Operating Reserve, of at least $6,250,000 in fiscal year 2008, to continue the program under this section in the event the fees collected in any subsequent fiscal year pursuant to subsection (a)(1) do not generate the fee revenue amount established for that fiscal year.

"(2) FEE SETTING.—The Secretary shall establish the operating reserve fee under subsection (a)(2)(A) for each person required to pay the fee by multiplying the number of DTC advertisements identified by that person pursuant to subsection (a)(1)(C) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year, except that in no case shall the operating reserve fee assessed be less than the operating reserve fee assessed if the person had first participated in the program under this section in fiscal year 2008.

"(3) USE OF OPERATING RESERVE.—The Secretary may use funds from the reserves only to the extent necessary in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsections (b) and (c) and the amount of fees actually collected for that fiscal year pursuant to subsection (a)(1), or to pay costs of ending the program under this section if it is terminated pursuant to subsection (f) or not reauthorized beyond fiscal year 2012.

"(4) REFUND OF OPERATING RESERVES.—Within 120 days after the end of fiscal year 2012, or if the program under this section ends early pursuant to subsection (f), the Secretary, after setting aside sufficient operating reserve amounts to terminate the program under this section, shall refund all amounts remaining in the operating reserve on a pro rata basis to each person that paid an operating reserve fee assessment. In no event shall the refund to any person exceed the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2). Deadline.

"(e) EFFECT OF FAILURE TO PAY FEES.—Notwithstanding any other requirement, a submission for advisory review of a DTC advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.

"(f) EFFECT OF INADEQUATE FUNDING OF PROGRAM.—

"(1) INITIAL FUNDING.—If on November 1, 2007, or 120 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, whichever is later, Effective date.

the Secretary has not received at least $11,250,000 in advisory review fees and operating reserve fees combined, the program under this section shall not commence and all collected fees shall be refunded.

Effective date. Notification.

"(2) LATER FISCAL YEARS.—Beginning in fiscal year 2009, if, on November 1 of the fiscal year, the combination of the operating reserves, annual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years falls below $9,000,000, adjusted for inflation (as described in subsection (c)(1)), the program under this section shall terminate, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to terminate the program, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the program, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and finally, unused advisory review fees from the relevant fiscal year.

"(g) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

"(2) COLLECTIONS AND APPROPRIATION ACTS.—

"(A) IN GENERAL.—The fees authorized by this section—

"(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

"(ii) shall be available for obligation only if the amounts appropriated as budget authority for such fiscal year are sufficient to support a number of full-time equivalent review employees that is not fewer than the number of such employees supported in fiscal year 2007.

"(B) REVIEW EMPLOYEES.—For purposes of subparagraph (A)(ii), the term 'full-time equivalent review employees' means the total combined number of full-time equivalent employees in—

"(i) the Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration; and

"(ii) the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, Food and Drug Administration.

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the

fiscal year, as adjusted pursuant to subsection (c) and paragraph (4) of this subsection, plus amounts collected for the reserve fund under subsection (d).

"(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

"(h) DEFINITIONS.—For purposes of this section:

"(1) The term 'advisory review' means reviewing and providing advisory comments on DTC advertisements regarding compliance of a proposed advertisement with the requirements of this Act prior to its initial public dissemination.

"(2) The term 'advisory review fee' has the meaning indicated for such term in subsection (a)(1)(D).

"(3) The term 'carry over submission' means a submission for an advisory review for which a fee was paid in one fiscal year that is submitted for review in the following fiscal year.

"(4) The term 'direct-to-consumer television advertisement' means an advertisement for a prescription drug product (as defined in section 735(3)) intended to be displayed on any television channel for less than 3 minutes.

"(5) The term 'DTC advertisement' has the meaning indicated for such term in subsection (a)(1)(A).

"(6) The term 'operating reserve fee' has the meaning indicated for such term in subsection (a)(2)(A).

"(7) The term 'person' includes an individual, partnership, corporation, and association, and any affiliate thereof or successor in interest.

"(8) The term 'process for the advisory review of prescription drug advertising' means the activities necessary to review and provide advisory comments on DTC advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the program under this section that are not necessary for the advisory review of DTC advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

"(9) The term 'resources allocated for the process for the advisory review of prescription drug advertising' means the expenses incurred in connection with the process for the advisory review of prescription drug advertising for—

"(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors;

"(B) management of information, and the acquisition, maintenance, and repair of computer resources;

"(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies;

"(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

"(E) terminating the program under this section pursuant to subsection (f)(2) if that becomes necessary.

"(10) The term 'resubmission' means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised in response to the Secretary's comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

"(11) The term 'submission for advisory review' means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.".

SEC. 105. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.), as amended by section 104, is further amended by inserting after section 736A the following:

21 USC 379h–2.

"SEC. 736B. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) PERFORMANCE REPORT.—Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

"(b) FISCAL REPORT.—Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

Website.

"(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

"(d) REAUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) health care professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

"(A) publish a notice in the Federal Register requesting public input on the reauthorization; Federal Register, publication.

"(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site. Website.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register; Federal Register, publication.

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments. Deadline.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry. Website.

"(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made

by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

SEC. 106. SUNSET DATES.

21 USC 379g note.

(a) AUTHORIZATION.—The amendments made by sections 102, 103, and 104 cease to be effective October 1, 2012.

21 USC 379h–2.

(b) REPORTING REQUIREMENTS.—The amendment made by section 105 ceases to be effective January 31, 2013.

21 USC 379g note.

SEC. 107. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2007, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2007, regardless of the date of the enactment of this Act.

21 USC 379g note.

SEC. 108. SAVINGS CLAUSE.

Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g note), and notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 109. TECHNICAL AMENDMENT; CONFORMING AMENDMENT.

(a) Section 739 (21 U.S.C. 379j–11) is amended in the matter preceding paragraph (1) by striking "subchapter" and inserting "part".

(b) Paragraph (11) of section 739 (21 U.S.C. 379j–11) is amended by striking "735(9)" and inserting "735(11)".

Medical Device User Fee Amendments of 2007.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

SEC. 201. SHORT TITLE; REFERENCES IN TITLE; FINDING.

21 USC 301 note.

(a) SHORT TITLE.—This title may be cited as the "Medical Device User Fee Amendments of 2007".

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

21 USC 379i note.

(c) FINDING.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy

and Commerce of the House of Representatives, as set forth in the Congressional Record.

Subtitle A—Fees Related to Medical Devices

SEC. 211. DEFINITIONS.

21 USC 379i.

Section 737 is amended—

(1) in the matter preceding paragraph (1), by striking "For purposes of this subchapter" and inserting "For purposes of this part";

(2) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (8), (9), (10), and (12), respectively;

(3) by inserting after paragraph (4) the following:

"(5) The term '30-day notice' means a notice under section 515(d)(6) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

"(6) The term 'request for classification information' means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

"(7) The term 'annual fee', for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.";

(4) in paragraph (10), as so redesignated—

(A) by striking "April of the preceding fiscal year" and inserting "October of the preceding fiscal year"; and

(B) by striking "April 2002" and inserting "October 2001";

(5) by inserting after paragraph (10), as so amended, the following:

"(11) The term 'person' includes an affiliate thereof."; and

(6) by inserting after paragraph (12), as so redesignated, the following:

"(13) The term 'establishment subject to a registration fee' means an establishment that is required to register with the Secretary under section 510 and is one of the following types of establishments:

"(A) MANUFACTURER.—An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

"(B) SINGLE-USE DEVICE REPROCESSOR.—An establishment that, within the meaning of section 201(ll)(2)(A), performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.

"(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.".

SEC. 212. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(A) in paragraph (1), by striking "Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002" and inserting "Beginning in fiscal year 2008"; and

(B) by amending the designation and heading of paragraph (2) to read as follows:

"(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—".

(2) FEE AMOUNTS.—Section 738(a)(2)(A) (21 U.S.C. 379j(a)(2)(A)) is amended—

(A) in clause (iii), by striking "a fee equal to the fee that applies" and inserting "a fee equal to 75 percent of the fee that applies";

(B) in clause (iv), by striking "21.5 percent" and inserting "15 percent";

(C) in clause (v), by striking "7.2 percent" and inserting "7 percent";

(D) by redesignating clauses (vi) and (vii) as clauses (vii) and (viii), respectively;

(E) by inserting after clause (v) the following:

"(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).";

(F) in clause (viii), as so redesignated—

(i) by striking "1.42 percent" and inserting "1.84 percent"; and

(ii) by striking ", subject to any adjustment under subsection (e)(2)(C)(ii)"; and

(G) by inserting after such clause (viii) the following:

"(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

"(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).".

(3) PAYMENT.—Section 738(a)(2)(C) (21 U.S.C. 379j(a)(2)(C)) is amended to read as follows:

"(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 515(c)(4) shall pay such fees upon submission of the first portion of such applications.".

(4) REFUNDS.—Section 738(a)(2)(D) (21 U.S.C. 379j(a)(2)(D)) is amended—

(A) in clause (iii), by striking the last two sentences; and

(B) by adding after clause (iii) the following:

"(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for an application submitted

under section 515(c)(4) that is withdrawn before a second portion is submitted and before a first action on the first portion.

"(v) LATER WITHDRAWN MODULAR APPLICATIONS.—If an application submitted under section 515(c)(4) is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

"(vi) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.".

(5) ANNUAL ESTABLISHMENT REGISTRATION FEE.—Section 738(a) (21 U.S.C. 379j(a)) is amended by adding after paragraph (2) the following:

"(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 510 beginning with its registration for fiscal year 2008.

"(B) EXCEPTION.—No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

"(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 510.".

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (e), and (h) the fees under subsection (a) shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Application	$185,000	$200,725	$217,787	$236,298	$256,384
Establishment Registration	$1,706	$1,851	$2,008	$2,179	$2,364.".

(c) ANNUAL FEE SETTING.—

(1) IN GENERAL.—Section 738(c) (21 U.S.C. 379j(c)(1)) is amended—

(A) in the subsection heading, by striking "Annual Fee Setting" and inserting "ANNUAL FEE SETTING"; and

(B) in paragraph (1), by striking the last sentence.

(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT FEE.—Section 738(c) (21 U.S.C. 379j(c)), as amended by paragraph (1), is further amended—

(A) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(B) by inserting after paragraph (1) the following:

"(2) ADJUSTMENT.—

"(A) IN GENERAL.—When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is fewer than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

Federal Register, publication.

"(B) PUBLICATION.—For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination."; and

(C) in paragraph (4), as redesignated by this paragraph, in subparagraph (A)—

(i) by striking "For fiscal years 2006 and 2007, the Secretary" and inserting "The Secretary"; and

(ii) by striking "for the first month of fiscal year 2008" and inserting "for the first month of the next fiscal year".

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL.—

(1) IN GENERAL.—Section 738(d)(1) (21 U.S.C. 379j(d)(1)) is amended—

(A) by striking ", partners, and parent firms"; and

(B) by striking "clauses (i) through (vi) of subsection (a)(2)(A)" and inserting "clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)".

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—Section 738(d)(2)(A) (21 U.S.C. 379j(d)(2)(A)) is amended by striking ", partners, and parent firms".

(B) EVIDENCE OF QUALIFICATION.—Section 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is amended—

(i) by striking "(B) EVIDENCE OF QUALIFICATION.—An applicant" and inserting the following:

"(B) EVIDENCE OF QUALIFICATION.—

"(i) IN GENERAL.—An applicant";

(ii) by striking "The applicant shall support its claim" and inserting the following:

"(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim";

(iii) by striking ", partners, and parent firms" each place it appears;

(iv) by striking the last sentence and inserting "If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates."; and

(v) by adding at the end the following:

"(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.".

Certification. Federal Register, publication.

(3) REDUCED FEES.—Section 738(d)(2)(C) (21 U.S.C. 379j(d)(2)(C)) is amended to read as follows:

"(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

"(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or periodic reporting concerning a class III device; and

"(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.".

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—Section 738(e)(1) (21 U.S.C. 379j(e)(1)) is amended—

(A) by striking "2004" and inserting "2008"; and

(B) by striking "(a)(2)(A)(vii)" and inserting "(a)(2)(A)(viii)".

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—Section 738(e)(2)(A) (21 U.S.C. 379j(e)(2)(A)) is amended by striking ", partners, and parent firms".

(B) EVIDENCE OF QUALIFICATION.—Section 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(B)) is amended—

(i) by striking "(B) EVIDENCE OF QUALIFICATION.—An applicant" and inserting the following:

"(B) EVIDENCE OF QUALIFICATION.—

"(i) IN GENERAL.—An applicant";

(ii) by striking "The applicant shall support its claim" and inserting the following:

"(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim";

(iii) by striking ", partners, and parent firms" each place it appears;

(iv) by striking the last sentence and inserting "If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates."; and

(v) by adding at the end the following:

Certification.
Federal Register, publication.

"(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.".

(3) REDUCED FEES.—Section 738(e)(2)(C) (21 U.S.C. 379j(e)(2)(C)) is amended to read as follows:

"(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).".

(f) EFFECT OF FAILURE TO PAY FEES.—Section 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

"(f) EFFECT OF FAILURE TO PAY FEES.—

"(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

"(2) NO REGISTRATION.—Registration information submitted under section 510 by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.".

(g) CONDITIONS.—Section 738(g) (21 U.S.C. 379j(g)) is amended—

(1) by striking paragraph (1) and inserting the following:

"(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

"(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $205,720,000 multiplied by the adjustment factor applicable to such fiscal year; or

"(B) fees were not assessed under subsection (a) for the previous fiscal year."; and

(2) by amending paragraph (2) to read as follows:

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.".

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(3) AUTHORIZATIONS OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

"(A) $48,431,000 for fiscal year 2008;

"(B) $52,547,000 for fiscal year 2009;

"(C) $57,014,000 for fiscal year 2010;

"(D) $61,860,000 for fiscal year 2011; and

"(E) $67,118,000 for fiscal year 2012.".

(2) OFFSET.—Section 738(h)(4) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011, exceeds the amount of fees specified in aggregate in paragraph (3) for these four fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.".

SEC. 213. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 3 of subchapter C of chapter VII is amended by inserting after section 738 the following:

21 USC 379j–1.

"SEC. 738A. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) REPORTS.—

"(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

"(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

Website.

"(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

"(b) REAUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) health care professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

"(A) publish a notice in the Federal Register requesting public input on the reauthorization; Federal Register, publication.

"(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site. Website.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register; Federal Register, publication.

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments. Deadline.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry. Website.

"(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

21 USC 379i note.

SEC. 214. SAVINGS CLAUSE.

Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), and notwithstanding the amendments made by this subtitle, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this subtitle, shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 215. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS FOR POSTMARKET SAFETY INFORMATION.

For the purpose of collecting, developing, reviewing, and evaluating postmarket safety information on medical devices, there are authorized to be appropriated to the Food and Drug Administration, in addition to the amounts authorized by other provisions of law for such purpose—

(1) $7,100,000 for fiscal year 2008;
(2) $7,455,000 for fiscal year 2009;
(3) $7,827,750 for fiscal year 2010;
(4) $8,219,138 for fiscal year 2011; and
(5) $8,630,094 for fiscal year 2012.

21 USC 379i note.

SEC. 216. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect on October 1, 2007, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all premarket applications, premarket reports, supplements, 30-day notices, and premarket notification submissions received on or after October 1, 2007, regardless of the date of the enactment of this Act.

21 USC 379i note.

SEC. 217. SUNSET CLAUSE.

The amendments made by this subtitle cease to be effective October 1, 2012, except that section 738A of the Federal Food, Drug, and Cosmetic Act (regarding annual performance and financial reports) ceases to be effective January 31, 2013.

Subtitle B—Amendments Regarding Regulation of Medical Devices

SEC. 221. EXTENSION OF AUTHORITY FOR THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 523(c) (21 U.S.C. 360m(c)) is amended by striking "2007" and inserting "2012".

SEC. 222. REGISTRATION.

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 360(b)) is amended—

(1) by striking "(b) On or before" and inserting "(b)(1) On or before";

(2) by striking "or a device or devices"; and

(3) by adding at the end the following:

"(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.".

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by striking "On or before December 31" and all that follows and inserting the following: "Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

"(A) upon first engaging in any such activity, immediately register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation; and

"(B) each establishment subject to the requirements of subparagraph (A) shall thereafter—

"(i) with respect to drugs, register with the Secretary on or before December 31 of each year; and

"(ii) with respect to devices, register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.".

SEC. 223. FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED, PREPARED, PROPAGATED, AND COMPOUNDED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.

Reports. Deadlines.

Section 510(j)(2) (21 U.S.C. 360(j)(2)) is amended, in the matter preceding subparagraph (A), by striking "Each person" and all that follows through "the following information:" and inserting "Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:".

SEC. 224. ELECTRONIC REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended to read as follows:

"(p) Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.".

SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

Study.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the appropriate use of the process under section 510(k) of the Federal Food, Drug, and Cosmetic Act as part of the device classification process to determine whether a new device is as safe and effective as a classified device.

(b) CONSIDERATION.—In determining the effectiveness of the premarket notification and classification authority under section 510(k) and subsections (f) and (i) of section 513 of the Federal Food, Drug, and Cosmetic Act, the study under subsection (a) shall consider the Secretary of Health and Human Services's evaluation of the respective intended uses and technologies of such devices, including the effectiveness of such Secretary's comparative assessment of technological characteristics such as device materials, principles of operations, and power sources.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

SEC. 226. UNIQUE DEVICE IDENTIFICATION SYSTEM.

(a) IN GENERAL.—Section 519 (21 U.S.C. 360i) is amended—

(1) by redesignating subsection (f) as subsection (g); and

(2) by inserting after subsection (e) the following:

"Unique Device Identification System

Regulations.

"(f) The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.".

(b) CONFORMING AMENDMENT.—Section 303 (21 U.S.C. 333) is amended—

(1) by redesignating the subsection that follows subsection (e) as subsection (f); and

(2) in paragraph (1)(B)(ii) of subsection (f), as so redesignated, by striking "519(f)" and inserting "519(g)".

SEC. 227. FREQUENCY OF REPORTING FOR CERTAIN DEVICES.

Subparagraph (B) of section 519(a)(1) (21 U.S.C. 360i(a)(1)) is amended by striking "were to recur;" and inserting the following: "were to recur, which report under this subparagraph—

"(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is—

"(I) a class III device;

"(II) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

Federal Register, publication.

"(III) a type of device which the Secretary has, by notice published in the Federal Register or letter to the person who is the manufacturer

or importer of the device, indicated should be subject to such part 803 in order to protect the public health;

"(ii) shall, if the device is not subject to clause (i), be submitted in accordance with criteria established by the Secretary for reports made pursuant to this clause, which criteria shall require the reports to be in summary form and made on a quarterly basis; or

"(iii) shall, if the device is imported into the United States and for which part 803 of title 21, Code of Federal Regulations (or successor regulations) requires an importer to submit a report to the manufacturer, be submitted by the importer to the manufacturer in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations)".

SEC. 228. INSPECTIONS BY ACCREDITED PERSONS.

Section 704(g) (21 U.S.C. 374(g)) is amended—

(1) in paragraph (1), by striking "Not later than one year after the date of the enactment of this subsection, the Secretary" and inserting "The Secretary";

(2) in paragraph (2), by—

(A) striking "Not later than 180 days after the date of enactment of this subsection, the Secretary" and inserting "The Secretary"; and

(B) striking the fifth sentence;

(3) in paragraph (3), by adding at the end the following:

"(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration. Notification. Deadline.

"(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).";

(4) by amending paragraph (6) to read as follows:

"(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

"(i) The Secretary classified the results of the most recent inspection of the establishment as 'no action indicated' or 'voluntary action indicated'.

"(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

"(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

"(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

"(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

"(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

"(aa) at least 1 of such devices is marketed in the United States; and

"(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

Deadline. "(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—

"(I) denies clearance to participate as provided under subparagraph (C); or

"(II) makes a request under clause (ii).

"(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

"(I) compliance data for the establishment in accordance with clause (iii)(I); or

"(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

Deadline. The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

"(iii)(I) The compliance data to be submitted by the owner or operator of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

"(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

Deadline. "(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues

a response that denies clearance to participate as provided under subparagraph (C).

"(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

"(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

"(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

"(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii). Notification. Applicability.

"(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree."; Deadline.

(5) in paragraph (7)—

(A) in subparagraph (A), by striking "(A) Persons" and all that follows through the end and inserting the following: "(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary."; and Records. Reports.

(B) by adding at the end the following:

Audits.

"(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods."; and

(6) in paragraph (10)(C)(iii), by striking "based" and inserting "base".

SEC. 229. STUDY OF NOSOCOMIAL INFECTIONS RELATING TO MEDICAL DEVICES.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on—

(1) the number of nosocomial infections attributable to new and reused medical devices; and

(2) the causes of such nosocomial infections, including the following:

(A) Reprocessed single-use devices.

(B) Handling of sterilized medical devices.

(C) In-hospital sterilization of medical devices.

(D) Health care professionals' practices for patient examination and treatment.

(E) Hospital-based policies and procedures for infection control and prevention.

(F) Hospital-based practices for handling of medical waste.

(G) Other causes.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

(c) DEFINITION.—In this section, the term "nosocomial infection" means an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital.

SEC. 230. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall determine—

(1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and

(2)(A) whether modifying the warning label required on tanning beds to read, "Ultraviolet radiation can cause skin cancer", or any other additional warning, would communicate the risks of indoor tanning more effectively; or

(B) whether there is no warning that would be capable of adequately communicating such risks.

(b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing to determine consumer understanding of label warnings.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

Pediatric Medical Device Safety and Improvement Act of 2007.

SEC. 301. SHORT TITLE.

21 USC 301 note.

This title may be cited as the "Pediatric Medical Device Safety and Improvement Act of 2007".

SEC. 302. TRACKING PEDIATRIC DEVICE APPROVALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515 the following:

"SEC. 515A. PEDIATRIC USES OF DEVICES.

21 USC 360e–1.

"(a) NEW DEVICES.—

"(1) IN GENERAL.—A person that submits to the Secretary an application under section 520(m), or an application (or supplement to an application) or a product development protocol under section 515, shall include in the application or protocol the information described in paragraph (2).

"(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

"(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

"(B) the number of affected pediatric patients.

"(3) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

"(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

"(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

"(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v); and

"(D) the review time for each device described in subparagraphs (A), (B), and (C).

"(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

"(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

"(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.

"(c) PEDIATRIC SUBPOPULATION.—For purposes of this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).".

SEC. 303. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (3), by striking "No" and inserting "Except as provided in paragraph (6), no";

(2) in paragraph (5)—

(A) by inserting ", if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met," after "public health"; and

(B) by adding at the end the following: "If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing."; and

(3) by striking paragraph (6) and inserting after paragraph (5) the following new paragraphs:

"(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

"(i)(I) The device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

"(II) The device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subclause (I) prior to the date of the enactment of the Pediatric Medical Device Safety and Improvement Act of 2007.

"(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the Secretary when the Secretary grants such exemption. The annual distribution number shall

be based on the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number, the number of individuals likely to use the device, and the number of devices reasonably necessary to treat such individuals. In no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

"(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii). Notification.

"(iv) The request for such exemption is submitted on or before October 1, 2012. Deadline.

"(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

"(C) A person may petition the Secretary to modify the annual distribution number specified by the Secretary under subparagraph (A)(ii) with respect to a device if additional information on the number of individuals affected by the disease or condition arises, and the Secretary may modify such number but in no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

"(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification. Applicability.

"(E)(i) In this subsection, the term 'pediatric patients' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

"(ii) In this subsection, the term 'pediatric subpopulation' means 1 of the following populations:

"(I) Neonates.

"(II) Infants.

"(III) Children.

"(IV) Adolescents.

"(7) The Secretary shall refer any report of an adverse event regarding a device for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.

"(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee Annual review.

of all devices described in paragraph (6) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.".

(b) REPORT.—Not later than January 1, 2012, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a device to profit from such device pursuant to section 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amended by subsection (a)), including—

(1) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—

(A) exemptions granted under such section 520(m)(2) for pediatric devices; and

(B) applications approved under section 515 of such Act (21 U.S.C. 360e) for devices intended to treat, diagnose, or cure conditions that occur in pediatric patients or for devices labeled for use in a pediatric population;

(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated size of the pediatric patient population for each condition or disease;

(3) the costs of purchasing pediatric devices, based on a representative sampling of children's hospitals;

(4) the extent to which the costs of such devices are covered by health insurance;

(5) the impact, if any, of allowing profit on access to such devices for patients;

(6) the profits made by manufacturers for each device that receives an exemption;

(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

(8) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and whether any modifications to such section 520(m)(6) (as amended by subsection (a)) should be made;

(9) existing obstacles to pediatric device development; and

(10) an evaluation of the demonstration grants described in section 305, which shall include an evaluation of the number of pediatric medical devices—

(A) that have been or are being studied in children; and

(B) that have been submitted to the Food and Drug Administration for approval, clearance, or review under such section 520(m) (as amended by this Act) and any regulatory actions taken.

Deadline. 21 USC 360j note.

(c) GUIDANCE.—Not later than 180 days after the date of the enactment of this Act, the Commissioner of Food and Drugs shall issue guidance for institutional review committees on how to evaluate requests for approval for devices for which a humanitarian

device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

SEC. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RESEARCH.

(a) CONTACT POINT FOR AVAILABLE FUNDING.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (21), by striking "and" after the semicolon at the end;

(2) in paragraph (22), by striking the period at the end and inserting "; and"; and

(3) by inserting after paragraph (22) the following:

"(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.".

(b) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, the Director of the National Institutes of Health, and the Director of the Agency for Healthcare Research and Quality, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a plan for expanding pediatric medical device research and development. In developing such plan, the Secretary of Health and Human Services shall consult with individuals and organizations with appropriate expertise in pediatric medical devices. Deadline.

(2) CONTENTS.—The plan under paragraph (1) shall include—

(A) the current status of federally funded pediatric medical device research;

(B) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(C) a research agenda for improving pediatric medical device development and Food and Drug Administration clearance or approval of pediatric medical devices, and for evaluating the short- and long-term safety and effectiveness of pediatric medical devices.

SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY. 42 USC 282 note.

(a) IN GENERAL.— Deadline.

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

(4) assessing the scientific and medical merit of proposed pediatric device projects; and

(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.

(d) COORDINATION.—

(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act, as added by section 304(a) of this Act; and

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

Reports.

(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $6,000,000 for each of fiscal years 2008 through 2012.

SEC. 306. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section 6(b) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(b)) is amended by inserting ", including increasing pediatric access to medical devices" after "pediatric issues".

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by inserting "(including drugs and biological products) and medical devices" after "therapeutics"; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting "(including drugs and biological products) and medical devices" after "therapeutics"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "and 505B" and inserting "505B, 510(k), 515, and 520(m)";

(ii) by striking subparagraph (B) and inserting the following:

"(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions;"; and

(iii) in subparagraph (C), by inserting "(including drugs and biological products) and medical devices" after "therapeutics".

SEC. 307. POSTMARKET SURVEILLANCE.

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) by amending the section heading and designation to read as follows:

"SEC. 522. POSTMARKET SURVEILLANCE.";

(2) by striking subsection (a) and inserting the following:

"(a) POSTMARKET SURVEILLANCE.—

"(1) IN GENERAL.—

"(A) CONDUCT.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

"(i) the failure of which would be reasonably likely to have serious adverse health consequences;

"(ii) that is expected to have significant use in pediatric populations; or

"(iii) that is intended to be—

"(I) implanted in the human body for more than 1 year; or

"(II) a life-sustaining or life-supporting device used outside a device user facility.

"(B) CONDITION.—The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).

"(2) RULE OF CONSTRUCTION.—The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act."; and

(3) in subsection (b)—

(A) by striking "(b) SURVEILLANCE APPROVAL.—Each" and inserting the following:

"(b) SURVEILLANCE APPROVAL.—

"(1) IN GENERAL.—Each";

(B) by striking "The Secretary, in consultation" and inserting "Except as provided in paragraph (2), the Secretary, in consultation";

(C) by striking "Any determination" and inserting "Except as provided in paragraph (2), any determination"; and

(D) by adding at the end the following:

"(2) LONGER SURVEILLANCE FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device.

"(c) DISPUTE RESOLUTION.—A manufacturer may request review under section 562 of any order or condition requiring postmarket surveillance under this section. During the pendency of such review, the device subject to such a postmarket surveillance order or condition shall not, because of noncompliance with such order or condition, be deemed in violation of section 301(q)(1)(C), adulterated under section 501(f)(1), misbranded under section 502(t)(3), or in violation of, as applicable, section 510(k) or section 515, unless deemed necessary to protect the public health.".

Pediatric Research Equity Act of 2007.

TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

21 USC 301 note.

SEC. 401. SHORT TITLE.

This title may be cited as the "Pediatric Research Equity Act of 2007".

SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQUITY ACT.

(a) IN GENERAL.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended to read as follows:

"SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration,

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate

formulations for each age group for which the assessment is required, that are adequate—

"(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

"(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

"(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

"(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

"(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.

"(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262).

"(3) DEFERRAL.—

"(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

"(i) the Secretary finds that—

"(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

"(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

"(III) there is another appropriate reason for deferral; and

"(ii) the applicant submits to the Secretary—

"(I) certification of the grounds for deferring the assessments;

"(II) a description of the planned or ongoing studies;

"(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

"(IV) a timeline for the completion of such studies.

"(B) ANNUAL REVIEW.—

"(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

"(I) Information detailing the progress made in conducting pediatric studies.

"(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

Website.

"(ii) PUBLIC AVAILABILITY.—The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration.

"(4) WAIVERS.—

"(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

"(II) is not likely to be used in a substantial number of pediatric patients.

"(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible

to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

Public information. Website.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

"(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—After providing notice in the form of a letter (that, for a drug approved under section 505, references a declined written request under section 505A for a labeled indication which written request is not referred under section 505A(n)(1)(A) to the Foundation of the National Institutes of Health for the pediatric studies), the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act to submit by a specified date the assessments described in subsection (a)(2), if the Secretary finds that—

"(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

"(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

"(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

"(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.

"(2) WAIVERS.—

"(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

"(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii)(I) the drug or biological product—

"(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

"(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

Public information. Website.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

"(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines that—

"(1) if approved, the drug or biological product could represent an improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

"(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

"(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit an assessment described in subsection (a)(2), or a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

"(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

"(2) the failure to submit the assessment or request shall not be the basis for a proceeding—

"(A) to withdraw approval for a drug under section 505(e); or

"(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.

"(e) MEETINGS.—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—

"(1) information that the sponsor submits on plans and timelines for pediatric studies; or

"(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

"(f) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS.—

"(1) REVIEW.—Beginning not later than 30 days after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall utilize the internal committee established under section 505C to provide consultation to reviewing divisions on all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section and all deferral and waiver requests granted pursuant to this section. Deadline.

"(2) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

"(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (4) or (5), which members of the committee participated in such activity.

"(4) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS.—Consultation on pediatric plans and assessments by the committee referred to in paragraph (1) pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section. The committee shall review all requests for deferrals and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review.

"(5) RETROSPECTIVE REVIEW OF PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—Not later than 1 year after the date of the enactment of the Pediatric Research Equity Act of 2007, the committee referred to in paragraph (1) shall conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since the enactment of the Pediatric Research Equity Act of 2003. Such review shall include an Deadline.

Recommendations.

analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on such review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section.

Public information. Website.

"(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

"(A) the number of assessments conducted under this section;

"(B) the specific drugs and biological products and their uses assessed under this section;

"(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

"(D) the total number of deferrals requested and granted under this section and, if granted, the reasons for such deferrals, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);

"(E) the number of waivers requested and granted under this section and, if granted, the reasons for the waivers;

"(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulation was not developed;

"(G) the labeling changes made as a result of assessments conducted under this section;

"(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (h)(2);

"(I) an annual summary of information submitted pursuant to subsection (a)(3)(B); and

"(J) the number of times the committee referred to in paragraph (1) made a recommendation to the Secretary under paragraph (4) regarding priority review, the number of times the Secretary followed or did not follow such a recommendation, and, if not followed, the reasons why such a recommendation was not followed.

"(g) LABELING CHANGES.—

"(1) DISPUTE RESOLUTION.—

Deadline.

"(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement—

"(i) the Commissioner shall request that the sponsor of the application make any labeling change

that the Commissioner determines to be appropriate; and

"(ii) if the sponsor does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee. Deadline.

"(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall— Deadline.

"(i) review the pediatric study reports; and

"(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

"(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate. Deadline.

"(D) MISBRANDING.—If the sponsor of the application or supplement, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded. Deadline.

"(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

"(2) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective in pediatric populations or subpopulations, including whether such assessment results are inconclusive, the Secretary shall order the label of such product to include information about the results of the assessment and a statement of the Secretary's determination.

"(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

"(1) IN GENERAL.—Not later than 210 days after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments, and shall post such assessments on the Web site of the Food and Drug Administration. Deadline. Public information. Website.

"(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall require that the sponsors of the assessments that result in labeling Effective date.

changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(H) distribute such information to physicians and other health care providers.

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

"(i) ADVERSE EVENT REPORTING.—

Effective date.

"(1) REPORTING IN YEAR ONE.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, during the one-year period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to such reports.

"(2) REPORTING IN SUBSEQUENT YEARS.—Following the one-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

"(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

"(j) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

"(k) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.

"(l) INSTITUTE OF MEDICINE STUDY.—

Deadline.
Contracts.
Reports.

"(1) IN GENERAL.—Not later than three years after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to this section or precursor regulations since 1997 and labeling changes made as a result of such studies.

"(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, the number and type of pediatric adverse events, and ethical issues in pediatric clinical trials.

"(3) REPRESENTATIVE SAMPLE.—The Institute of Medicine may devise an appropriate mechanism to review a representative sample of studies conducted pursuant to this section from each review division within the Center for Drug Evaluation and Research in order to make the requested assessment.

"(m) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(q).".

(b) APPLICABILITY.— 21 USC 355c note.

(1) IN GENERAL.—Notwithstanding subsection (h) of section 505B of the Federal Food, Drug and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, a pending assessment, including a deferred assessment, required under such section 505B shall be deemed to have been required under section 505B of the Federal Food, Drug and Cosmetic Act as in effect on or after the date of the enactment of this Act.

(2) CERTAIN ASSESSMENTS AND WAIVER REQUESTS.—An assessment pending on or after the date that is 1 year prior to the date of the enactment of this Act shall be subject to the tracking and disclosure requirements established under such section 505B, as in effect on or after such date of enactment, except that any such assessments submitted or waivers of such assessments requested before such date of enactment shall not be subject to subsections (a)(4)(C), (b)(2)(C), (f)(6)(F), and (h) of such section 505B.

SEC. 403. ESTABLISHMENT OF INTERNAL COMMITTEE.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

"SEC. 505C. INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS. Establishment. 21 USC 355d.

"The Secretary shall establish an internal committee within the Food and Drug Administration to carry out the activities as described in sections 505A(f) and 505B(f). Such internal committee shall include employees of the Food and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry, and other individuals designated by the Secretary.".

SEC. 404. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.

Not later than January 1, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to the Congress a report that addresses the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested and properly labeled. Such report shall include—

(1) the number and importance of drugs and biological products for children that are being tested as a result of the amendments made by this title and title V and the importance

for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs and biological products for children that are not being tested for their use notwithstanding the provisions of this title and title V and possible reasons for the lack of testing;

(3) the number of drugs and biological products for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this title, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee;

(4) any recommendations for modifications to the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act (42 U.S.C. 284m) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation; and

(5)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population; and

(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe.

Best Pharmaceuticals for Children Act of 2007.

TITLE V—BEST PHARMACEUTICALS FOR CHILDREN ACT OF 2007

21 USC 301 note.

SEC. 501. SHORT TITLE.

This title may be cited as the "Best Pharmaceuticals for Children Act of 2007".

SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT.

(a) PEDIATRIC STUDIES OF DRUGS.—

(1) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended to read as follows:

"SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

"(a) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at the discretion of the Secretary, may include preclinical studies.

"(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall